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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,652	03/13/2001	D. Laksen Sirimanne	412692000401	4202

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EXAMINER
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JUNG, WILLIAM C

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/805,652	<b>Applicant(s)</b> SIRIMANNE ET AL.	
	<b>Examiner</b> William Jung	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31, 33-35, 109 and 110 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31, 33-35, 109 and 110 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>14102005</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments with respect to claims 1-31, 33-35, 109, and 110 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-31, 33-35, 109, and 110 are rejected under 35 U.S.C. 102(e) as being anticipated by *Burbank et al* (US 6,161,034).

Burbank et al anticipate all claimed features in claims 1-31, 33-35, 109, and 110.

**Claims 1, 4, 14, 15, 26-28, 109, and 110:** Burbank et al disclose a subcutaneous cavity marking device comprising at least two separate implantable bioabsorbable bodies L and 10 adapted to be inserted into a subcutaneous cavity created by removing tissue (biopsy) and at least

one of the implantable material is marker for marking a particular section of the cavity (col. 3, lines 6-63; col. 4, line 14 – col. 5, line 11).

**Claims 2 and 3:** Burbank et al further disclose the marker material in claim where the x-ray detectable body comprises metal, stainless steel, and metal oxide (metal ion is equivalent to metal oxide or stainless steel or alloy) (col. 7, lines 47-62; col. 8, lines 35-45).

**Claims 5-8, 18-20, and 35:** Burbank et al disclose that the marker comprises of material such as bioabsorbable material made from polymer based radiopaque substances, collagen, cellulose material, protein, etc. as claimed. In addition, Burbank et al disclose that the implant/marker materials may include various phase where the materials are gaseous, gels, liquid, fluid, pellets or beads of materials in slurry or liquid suspension (see figure 3b). In addition, Burbank et al disclose that the group of radiopaque additive includes AgCl, AgI, BaCO<sub>3</sub>, BaSO<sub>4</sub>, K, CaCO<sub>3</sub>, ZnO, and Al<sub>2</sub>O<sub>3</sub> or any combination thereof (col. 12, lines 14-18).

**Claims 9 and 10:** Burbank et al disclose imaging of the markers with x-ray or ultrasound. Typically the ultrasound markers are microbubbles or microspheres (see above), although not explicitly disclosed in Burbank et al; it is inherent that the ultrasound application is coupled with ultrasound markers that are inherent properties of microbubbles (col. 10, lines 37-40).

**Claims 11 and 12:** Burbank et al illustrate in figures 2b o 2e where the radiomarkers are implanted with the use of mammographical imaging device.

**Claim 13:** Burbank et al disclose that the markers implanted in the soft tissue are palpable (col. 4, lines 25-35).

**Claims 16, 17, and 34:** Burbank et al disclose that the device disclosed above is used with therapeutic procedure, which includes radiotherapy, chemotherapy, etc. (col. 1, lines 6-12).

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**Claims 21-25, 29-31, and 33:** The limitations in claims 21-25, 29-31, and 33 provide structural or shape of the bioabsorbable markers where the functioning of the markers in view of the imaging or detector device do not differentiate the use. Therefore, the limitations in claims 21-25, 29-31, and 33 are merely a design choice.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

WCS

February 2, 2006

  
BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3737